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Intracameral moxifloxacin, cefuroxime, and vancomycin: spectra of activity, preparation, safety, and efficacy

Moxifloxacino, cefuroxima e vancomicina intracameral: espectro de atividade, preparo, segurança e eficácia

Moxifloxacino, cefuroxima y vancomicina intracameral: espectro de actividad, preparación, seguridad y eficacia

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ABSTRACT

In Brazil, the greatest barrier to the routine intracameral use of prophylactic antibiotics at the end of cataract surgery is the lack of a commercially available antibiotic preparation for intracameral use approved by the National Sanitary Surveillance Agency (ANVISA). The Literature Review Group of the Brazilian Society for Cataract and Refractive Surgery (ABCCR/BRASCS) chose this topic for update aiming to review aspects regarding the spectrum of activity, dosage, preparation, safety and efficacy of moxifloxacin, cefuroxime, and vancomycin, which are deemed the safest antibiotics for intracameral use.

Keywords:
Antibiotic Prophylaxis;
Anti-Bacterial Agents/ administration & dosage;
Cefuroxime;
Vancomycin;
Moxifloxacin

RESUMO

No Brasil, a maior barreira para o uso intracameral de antibiótico profilático rotineiro no final da cirurgia de catarata é a falta de uma preparação comercial de antibiótico para uso intracameral aprovada pela Agência Nacional de Vigilância Sanitária (ANVISA). O Grupo de Revisão da Literatura da Sociedade Brasileira de Catarata e Cirurgia Refrativa (ABCCR/ BRASCS) escolheu este tema para atualização pretendendo revisar aspectos dos espectros de atividade, dosagem e preparação, segurança e eficácia dos antibióticos moxifloxacino, cefuroxima e vancomicina, considerados os mais seguros para o uso intracameral.

Palavras-Chave:
Antibioticoprofilaxia;
Antibacterianos/administração & dosagem;
Cefuroxima;
Vancomicina;
Moxifloxacino

RESUMEN

En Brasil, la mayor barrera para el uso intracameral de antibiótico profiláctico rutinario al final de la cirugía de catarata es la falta de una preparación comercial de antibióticos para el uso intracameral aprobada por la Agencia Nacional de Vigilancia Sanitaria (ANVISA). El Grupo de Revisión de la Literatura de la Sociedad Brasileña de Catarata y Cirugía Refractiva (ABCCR/ BRASCS) ha elegido este tema para actualización, con vistas a revisar aspectos de los espectros de actividad, dosificación y preparación, seguridad y eficacia de los antibióticos moxifloxacino, cefuroxima y vancomicina, considerados los más seguros para el uso intracameral.

Palabras Clave:
Profilaxis Antibiótica;
Antibacterianos/administración & dosificación;
Cefuroxima;
Vancomicina;
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Bacterial endophthalmitis is a rare complication of cataract surgery. It occurs in 0.04% to 0.2% of cases [1,2] and is associated with high ocular morbidity and vision loss[2]. In the past, the source of endophthalmitis infection was not identified in most cases[3]. The multicenter Endophthalmitis Vitrectomy Study-EVS [4] showed that 82% of the endophthalmitis isolates were external ocular bacterial flora. The microorganisms most commonly found in endophthalmitis are Gram-positive bacteria (72.9%), Gram-negative bacteria (10.7%), and fungi (15.83%)[5]. The increase in life expectancy and population aging will lead to an increase in the prevalence of this postoperative complication if measures to reduce the risk are not implemented[3]. Prophylactic measures such as the treatment of ocular surface disorders before surgery, preoperative disinfection with povidone-iodine, thorough equipment sterilization, and the use of an intracameral antibiotic at the end of cataract surgery are essential to minimize the risk of postoperative infection[6,7,8,9]. Among the major limitations of using intracameral antibiotics in Brazil are the fact that there is no commercially available preparation for intracameral use that does not require manipulation and/or dilution, and the fact that the product has not been approved for this indication (off-label use). In this update we will cover aspects related to the spectrum of activity, preparation, safety, and efficacy of intracameral moxifloxacin, cefuroxime, and vancomycin administered at the end of cataract surgery for the prophylaxis of bacterial endophthalmitis.

Spectrum of activity

Braga-Mele et al.[6] indicated three antibiotics (moxifloxacin, cefuroxime, and vancomycin), whose safety and efficacy in intracameral use are adequately described in the literature. According to Javitt[7], considering that approximately three million cataract surgery procedures are performed annually in the US, the use of an intracameral antibiotic at the end of cataract surgery would potentially avoid the negative effect of postoperative endophthalmitis in approximately 2,000 of these eyes every year.

Moxifloxacin is a fourth-generation fluoroquinolone with broad-spectrum and potent activity, and not prone to inducing resistance. The antibiotic has good tissue penetration and excellent efficacy, especially against Gram-positive bacteria[8,10]. The antimicrobial activity of moxifloxacin occurs via a dual-targeting mechanism, inhibiting both DNA gyrase (Gram-negative bacteria) and topoisomerase (Gram-positive bacteria). Human cells do not have these enzymes, which makes them ideal targets for this antibiotic's activity. Because double mutations are rare, the preferential use of them could potentially limit the increase in resistance to them [11].

Cefuroxime (a second-generation cephalosporin) has a beta-lactam ring in its molecular structure that interferes with the final stage of bacterial cell wall formation. The beta-lactamases produced by S. aureus are penicillinases and do not affect cephalosporins; however, the beta-lactamases produced by Gram-negative bacteria inactivate many cephalosporins[11]. Cefuroxime has broad-spectrum activity and covers most Gram-positive and Gram-negative organisms associated with endophthalmitis following cataract surgery, with the exception of methicillin-resistant *Staphylococcus aureus* (MRSA)[7,12].

Vancomycin inhibits peptidoglycan layer biosynthesis during cell wall formation[11]. It is effective against methicillin-resistant *Staphylococcus* and penicillin-resistant *S. pneumoniae*. Vancomycin is a bactericidal antibiotic and virtually 100% of Gram-positive organisms that cause endophthalmitis following cataract surgery are susceptible to this antibiotic[6].

Dosage and preparation

Moxifloxacin eye drops (Vigamox® 0.5%, Alcon) is an isotonic, preservative-free commercial preparation . It has pH 6.8 and an osmolarity of approximately 290 mOsm/kg, values that are similar to those of the aqueous humor (pH 7.4 and 305 mOsm/kg)[6,10]. The intracameral use of this topic solution has not been associated with toxicity (intracameral use at 0.5% or diluted in a balanced saline solution at 50:50) [6,10].

Cefuroxime sodium is available in the European Union in vials containing 50 mg powder of cefuroxime (as 52.6 mg of cefuroxime sodium) for solution for injection (Aprokam®, Tea Pharmaceuticals)[12]. The preparation of the drug for intracameral use starts with the injection of 5 ml of preservative-free sterile saline solution into the Aprokam® vial to obtain a cefuroxime solution at a concentration of 10 mg/ml. Then, 0.1 ml of this solution (1 mg of cefuroxime) is aspirated using a 1-ml syringe and, lastly, a cannula is adapted to the syringe to inject the intracameral antibiotic. This solution has a pH and an osmotic pressure that are close to physiological values (pH 7.3 and osmolarity of 335 mOsm/kg).

In Brazil, cefuroxime sodium is available in vials containing 750 mg of cefuroxime (as 789 mg of cefuroxime sodium) in the form of a white to pale-yellow powder, together with an ampoule containing 6 ml of double-distilled water for intramuscular or intravenous use

(Zinacef®, GlaxoSmithKline Brasil Ltda.)[13]. For intracameral use only the content in the vial (750 mg of cefuroxime) is used, being initially diluted in 15 ml of preservative-free sterile saline solution to obtain a solution of cefuroxime with a concentration of 50 mg/ml. Subsequently, 1 ml of this solution is aspirated and 4 ml of sterile saline without preservative are added to obtain a solution of cefuroxime with a concentration of 10 mg/ml. A volume of 0.1 ml of this solution is aspirated for intracameral injection (1 mg of cefuroxime in 0.1 ml of injectable solution). Finally, a cannula is adapted for intracameral injection and the syringe is ready to be used. In Brazil, the intracameral use of cefuroxime is off-label[13].

Each vial of vancomycin (Vancocina®, Lilly) 500 mg powder (as 512.60 mg of vancomycin hydrochloride) comes with an ampoule of solvent (10 ml of preservative-free sterile saline solution) for intravenous injectable solution[14]. For intracameral use the content of the vial is reconstituted with 10 ml of preservative-free sterile saline solution. A volume of 2 ml is aspirated from this solution and further diluted in 8 ml of preservative-free sterile saline solution. The final solution has a concentration of 1 mg in 0.1 ml. A volume of 0.1 ml of this solution is aspirated for intracameral injection (1 mg of vancomycin in 0.1 ml of preservative-free sterile saline solution)[15].

Safety and efficacy

The intracameral use of **moxifloxacin** eye drops has not been associated with toxicity (intracameral use of moxifloxacin at 0.5% or diluted in balanced saline solution 50:50)[6]. Recently, 12 patients who inadvertently received an intracameral injection of another commercial solution of moxifloxacin at 0.5% (Moxeza®, Alcon) developed toxic anterior segment syndrome (TASS) after cataract surgery[6]. This medication contains xanthan gum, sorbitol, and tyloxapol, i.e., it has detergent and mucolytic properties and should therefore not be introduced in the anterior chamber [6,10]. The package leaflet of Moxeza® warns that the product is only indicated for ophthalmic topical use and cannot be injected in the subconjunctival space or introduced directly in the anterior chamber of the eye [6,10].

Kowalski et al.[16] did not find toxicity related to intracameral injection of Vigamox® solution for the prevention of endophthalmitis by *S. aureus* in an animal model (rabbit). Another study with patients showed that the intracameral use of moxifloxacin was safe at a dosage of 100 µg/0.1 ml or 250 µg/0.05 ml, obtained by diluting Vigamox®[17].

Silva et al.[18] studied the toxicity of intracameral fourth-generation fluoroquinolones in the corneal endothelium (besifloxacin, gatifloxacin, and moxifloxacin). The authors concluded that the intracameral injection of these antibiotics did not adversely affect the corneal endothelium. They observed, however, that longer contact between the antibiotics and endothelial cells promotes endothelial toxicity. In addition, they reported that the injection of intracameral antibiotics is associated with a shorter exposure of the corneal endothelium to the antibiotics depending on the rate of aqueous humor turnover. They indicated the need to assess the half-life of the antibiotics and the potential change in the rate of aqueous humor turnover induced by intracameral injection in order to determine the exact time of endothelial exposure to the antibiotics.

Many studies have shown that the intracameral use of 1.0 mg of **cefuroxime** is not associated with the loss of endothelial cells or macular edema [19,20,21]. Shahar et al.[22] reported that the intravitreal injection of 1.0 mg of cefuroxime was not toxic to the retina in rabbits. The side effects of cephalosporins are similar to those of penicillins and consist of hypersensitivity reactions: maculopapular rash, hives, fever, bronchospasm, anaphylaxis, and eosinophilia. There is an immune cross-reaction in approximately 20% of patients who are allergic to penicillin and, clinically, a lower rate of reaction to cephalosporin in those allergic to penicillin has been suggested (between 5% and 10%)[11]. However, there have been reports of anaphylactic reactions: two after the administration of a cefuroxime injection, one after an intracameral injection [23] and one after vitreal injection [24]. Fortunately, this reaction is very rare [6].

Yoeruek et al.[25] investigated the toxic effects of intracameral **vancomycin** and cefuroxime in human endothelial cells and did not find toxicity associated with the use of these antibiotics at the recommended clinical concentrations; however, they emphasized that the use of higher concentrations of these intracameral antibiotics could cause irreversible cell death.

The use of intracameral **vancomycin** has been implicated as a cause of cystoid macular edema. Axer-Siegel et al.[26] conducted a controlled clinical trial to evaluate the macula using fluorescein angiography and found an association between cystoid macular edema and the use of intracameral vancomycin in extracapsular cataract surgery. Ball and Barrett[27] conducted a controlled clinical trial to assess macular thickness using optical coherence tomography (OCT) and did not observe a significant increase in macular thickness with the use of intracameral vancomycin and gentamycin during cataract surgery.

Witkin et al.[28] published a study reporting that 11 eyes of six patients who previously underwent cataract surgery without complications and who received prophylactic intracameral vancomycin developed a hemorrhagic occlusive retinal vasculitis (HORV) syndrome between days 1 and 14 postoperatively. The authors reported that despite the aggressive treatment that included topical and systemic corticosteroids, intravitreal antibiotics (4 eyes), pars plana vitrectomia (4 eyes), intravitreal injection of anti-VEGF, and/or panretinal photocoagulation for retinal ischemia, the final visual acuity (VA) was lower than 20/100 in 8 of the 11 eyes. The authors suggested that the HORV syndrome could represent a late immune reaction similar to leukocytoclastic vasculitis induced by vancomycin. In addition, they suggested that early intervention with intravitreal injection of anti-VEGF and/or panretinal photocoagulation could prevent additional vision loss as a result of neovascular glaucoma. Rush et al.[29] used intracameral vancomycin in 9,836 consecutive cataract surgery procedures and did not find an association between adverse events (toxicity) and the use of the intracameral antibiotic. No patient in this study stopped using intracameral vancomycin due to an allergic reaction.

DISCUSSION

The intracameral use of antibiotics during cataract surgery has been reported since the 1990s [32]. During this period, cataract surgeons have experimented using many prophylactic intracameral antibiotics, but the majority prefer using cefuroxime, moxifloxacin, and vancomycin [30,32,33,34].

Shorstein et al. [35] conducted a study in the US that analyzed over 16,000 cataract surgery procedures. They observed that the rate of endophthalmitis was more than 22 times lower among those in which an intracameral injection of antibiotic was administered at the end of the procedure. Once again, these results confirm the data from the European Society of Cataract and Refractive Surgeons (ESCRS) 2007[36]. Therefore, the data published in the literature show that the prophylactic use of intracameral antibiotics should be a routine procedure in all cataract surgery procedures and, by extension, in other intraocular surgeries. This practice has already been established in Europe and in many other countries. However, in countries without access to the approved and commercially available preparations, such as Brazil, in addition to the fact that the use of intracameral antibiotics is off-label, there is the risk of incorrect preparation dosage.

With regard to the choice of antibiotic for intracameral use, there is no strong evidence or consensus in the literature on which is the best antibiotic[6]. Moxifloxacin has a broader spectrum of activity than cefuroxime as well as a concentration-dependent mechanism of action that may be advantageous for intracameral use [17]. However, the reviewed literature did not include controlled clinical studies that compared the efficacy of moxifloxacin with that of cefuroxime, thus not allowing to draw conclusions. We can, nevertheless, point out another advantage of moxifloxacin, which is that it is commercially available without preservatives (Vigamox®), thus allowing its intracameral use, although this form of use does not appear in its technical specifications (Vigamox®; Alcon Laboratories) [31].

Vancomycin is another alternative to cefuroxime. Murphy et al. [37] conducted a human pharmacokinetics study and reported surprisingly high and sustained levels of vancomycin in the aqueous humor after intracameral injection of vancomycin at the end of cataract surgery. The risk of developing bacterial resistance after the use of the intracameral antibiotic must be very small because the antibiotic is injected in an isolated ocular compartment. In this context, the study by Murphy et al. [37] showed that the levels of vancomycin were in fact high in the aqueous humor and remained so for approximately 24 hours when using a dosage of 1 mg of intracameral vancomycin.

The aim of this ABCCR/BRASCS updated guideline was to highlight all the robust evidence that exists in the literature in favor of the use of intracameral antibiotics to reduce the rate of bacterial post-cataract surgery endophthalmitis. An additional goal was to identify and break down the barriers to the establishment of this practice in Brazil.

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